

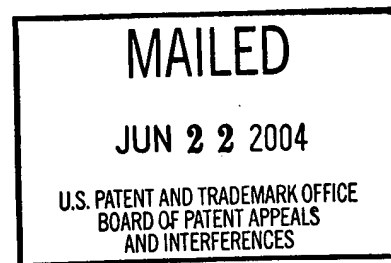
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

Ex parte JAGANNADHA K. SASTRY, RALPH B. ARLINGHAUS,  
CHRIS D. PLATSOUCAS, and PRAMOD N. NEHETE

Appeal No. 2004-1392  
Application No. 08/869,386<sup>1</sup>

ON BRIEF



Before, WINTERS, WILLIAM F. SMITH, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

REMAND TO THE EXAMINER

On consideration of the administrative file we find this case is not in condition for a decision on appeal. For the reasons that follow, we remand the application to the examiner to consider the following issues and to take appropriate action.

<sup>1</sup> This case is a divisional application of 07/945,865, which is the subject matter of In re Sastry, 285 F.3d 1378, 62 USPQ2d 1436 (Fed. Cir. 2002) (affirming the Board's finding of unpatentability under 35 U.S.C. § 103).

I. Appendices:

Appellants make reference to Appendix A – Appendix J. Brief, page 3. These appendices are not attached to the Brief, nor are they present in the administrative file. Specifically, we note:

Appendix A is asserted to be a reproduction of the claims on appeal. See Brief, page 4. This appendix is not part of the record before us for review.

Appendix B is asserted to be an amendment of claim 47 filed concurrently with the Brief. See Brief, page 4. It appears that Appendix B is a copy of the “Amendment After Final Rejection” entered into the record as Paper No. 18. Clarification is requested.

Appendix C is asserted to be a substitute specification. See Brief, page 5. the “Contents” section of the administrative file contains two entries listing a substitute specification. See Paper Nos. 17 and 18. The administrative file contains several papers titled “SUBSTITUTE SPECIFICATION.” None of these papers, however, refers to a Paper No. or a date of entry. Clarification is requested.

Appendix D is asserted to be the Fultz (1993) reference. See Brief, page 8. This reference appears to be relied upon to support appellants’ assertion that “chimpanzees are the accepted model for HIV infection, and are the preferred system for investigating methods of protection.” Id. This reference is not present in the administrative file.

Appendix E is asserted to be the Yarchoan and Broder (J. Enz. Inh. 1992) reference. See Brief, page 9. According to appellants’ “[t]he Action cites Yarchoan and Broder ... to support its contention that agents shown to block HIV infection of cells lack clinical efficacy and are subject to seemingly insurmountable problems that preclude their in vivo use.” This reference is not present in the administrative file.

Additionally, we note that page 3 of the Brief, identifies the Yarochoan et al. (1992) reference as Appendix H. Clarification is requested.

Further, we note that while the examiner appears to rely on this reference to support his rejection under 35 U.S.C. § 112, first paragraph (see Answer, page 5), this reference is not listed in the “Prior Art of Record” section of the Answer (see Answer, page 3). Clarification of this conflict is requested.

Appendix F is asserted to be the Gait (TIBTECH 1995) reference. See Brief, page 9. According to appellants' "[t]he Action cites ... Gait ... to support its contention that agents shown to block HIV infection of cells lack clinical efficacy and are subject to seemingly insurmountable problems that preclude their in vivo use." This reference is not present in the administrative file.

Additionally, we note that page 3 of the Brief, identifies the Gait and Karn (1995) reference as Appendix I. Clarification is requested.

Further, we note that while the examiner appears to rely on this reference to support his rejection under 35 U.S.C. § 112, first paragraph (see Answer, page 5), this reference is not listed in the "Prior Art of Record" section of the Answer (see Answer, page 3). Clarification of this conflict is requested.

Appendix G is asserted to be the Vitetta et al., United States Patent 5,767,072 ('072). See Brief, page 9. Vitetta appears to be relied upon by appellants to "demonstrate that a person of ordinary skill would be aware of methods for providing the peptides to a host to effectively inhibit cellular infection." Id. This patent is not present in the administrative file.

Additionally, we note that page 3 of the Brief, identifies '072 as Appendix E. Clarification is requested.

Appendix H is asserted to be the Sabatier et al., United States Patent 5,622,933 ('933). See Brief, page 9. Sabatier appears to be relied upon by appellants to "demonstrate that a person of ordinary skill would be aware of methods for providing the peptides to a host to effectively inhibit cellular infection." Id. This patent is not present in the administrative file.

Additionally, we note that page 3 of the Brief, identifies '933 as Appendix F. Clarification is requested.

Appendix I is asserted to be the FDA 257A document. See Brief, page 9. According to appellants this document demonstrates that "a peptide closely related to that disclosed in the instant invention, is currently undergoing phase II clinical trials as a means of preventing viral uptake." Id. This document is not present in the administrative file.

Additionally, we note that page 3 of the Brief, identifies FDA 257A as Appendix G. Clarification is requested.

Appendix J is asserted to be a "Table of Authorities." See Brief, page 3. This appendix is not present in the administrative file.

As set forth above, clarification of the administrative record is required in addition to supplementing the administrative file with the missing documents and

appendices. Accordingly, we encourage the examiner to work together with appellants' to correct this deficiency in the record presented for our review.

## II. What prior art is of record?

As set forth above, the examiner appears to rely on the Yarchoan (J. Enz. Inh. 1992) and Gait (TIBTECH 1995) to support his rejection under 35 U.S.C. § 112, first paragraph. See Answer, page 5. These references, however, are not listed in the "Prior Art of Record" section of the Answer. See Answer, page 3, section 9.

Similarly, the examiner appears to rely on Haynes (Science 1993) and Haynes, et al. (Ann. Med., 1996) to support his rejection under 35 U.S.C. § 112, first paragraph. See Answer, pages 7 and 10. Neither of these references are listed in the "Prior Art of Record" section of the Answer. See Answer, page 3, section 9. In addition, we note that neither of these references are part of the administrative file presented for our review.

We also note the examiner's statement (Answer, page 7, emphasis added), "as previously stated, Haynes (Science 1993) states that 'in spite of an extraordinary amount of work in search of an animal model for human AIDS[], no animal model exactly mirrors HIV infection'." Upon review of the Answer, we are unable to identify where the examiner "previously" made reference to Haynes (Science 1993). Clarification is requested.

## III. The scope of enablement rejection:

While we take no position on the merits, upon receipt of the administrative file, we encourage the examiner to take a step back and reconsider the pending

rejection under 35 U.S.C. § 112, first paragraph together with the prior art of record and Application No. 07/945,865, the parent of this application wherein the Board reversed a rejection under 35 U.S.C. § 112, first paragraph; see also Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999) (wherein our appellate reviewing court illustrated the type of fact finding which is necessary to determine whether a given claim is enabled or non-enabled).

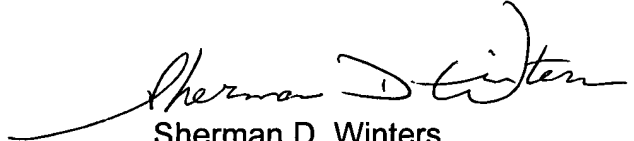
If after this review, the examiner is believes that the rejection under 35 U.S.C. § 112, first paragraph should be modified, the examiner should issue an appropriate Office action which clearly articulates the examiner's position.

#### CONCLUSION

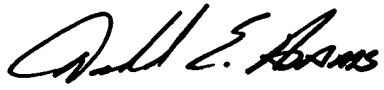
For the foregoing reasons this case is not in condition for a decision on appeal. Accordingly, we remand the application to the examiner to consider the aforementioned issues and to take appropriate action. Note that any further communication from the examiner that contains a revised rejection of the claims should provide appellants with a full and fair opportunity to respond.

This application, by virtue of its "special" status, requires an immediate action. MPEP § 708.01(D) (8<sup>th</sup> ed., rev. 1, Feb. 2003). It is important that the Board be informed promptly of any action affecting the appeal in this case.

REMANDED

  
Sherman D. Winters  
Administrative Patent Judge

  
William F. Smith  
Administrative Patent Judge

  
Donald E. Adams  
Administrative Patent Judge

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